

## REMARKS

This Amendment is responsive to the Final Office Action dated March 15, 2007. Applicants have added new claims 20-26. Claims 1-26 are pending in the present application.

### **Claim Rejection Under 35 U.S.C. § 112**

In the Final Office Action, the Examiner rejected claims 1-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses the rejection.

The Final Office Action stated that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner stated that the limitation “consisting essentially of” is lacking support in Examples 1 and 2, as cited by the Applicant. The Examiner reasoned that, although the examples do not positively recite stimulation of other organs, the examples also do not exclude stimulation of other organs.

In support of the rejection, the Examiner pointed to MPEP 2173.05(i), which states that any negative limitation or exclusionary proviso must have a basis in the original disclosure. On this basis, the Examiner concluded that the mere absence of a positive recitation is not a basis for an exclusion. Applicant respectfully disagrees that there is a lack of support for the limitation.

The rejection in question centers on support for the claim limitation added by the Applicants in an amendment. Regarding the requirements for support, section 2163(I)(B) of the MPEP states that “[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.” In view of the express, implicit and inherent disclosures of the specification, the written description requirement is satisfied if the original disclosure would have reasonably conveyed to one having ordinary skill in the art that an inventor had possession of the concept of what is claimed. *See Ex parte Parks*, 30 USPQ 1234, 1236 (Bd. Pat. App. & Inter. 1993); MPEP 2136. Applicant respectfully submits that the express, implicit and inherent disclosures of the specification, when read as a whole, support the claim limitation in question and satisfy the written description requirement.

As the Final Office Action states, the mere absence of a positive recitation is not a basis for an exclusion. However, Applicant's position is not relying on the mere absence of a positive recitation. Instead, Applicant asserts that the absence of a positive recitation in addition to the specification, read in its entirety, including Examples 1 and 2, supports the limitation "consisting essentially of." For instance, as the Examiner pointed out, Applicant's disclosure on page 9 states that "[t]he present methods can also be used in combination with electrostimulation of other parts of the gastrointestinal tract." Although the passage discloses the possibility of stimulation of the small intestine in combination with other parts of the gastrointestinal tract, by presenting it in the form of an option, the statement implicitly and inherently discloses other embodiments in which it is required that only the small intestine be stimulated.

This conclusion is bolstered by the fact that Examples 1 and 2 both disclose electrostimulation of only the small intestines, and particularly only the duodenum in Example 1, and not any other organs. Indeed, Example 1 refers specifically to duodenal electrical stimulation (DES) as the subject of the example, and describes the effects of DES in increasing gastric volume and reducing food intake. Further support is found in the passages previously cited by Applicants, which describe the treatment of obesity by providing electrostimulation to the small intestines, without mention of other areas of stimulation. Application, page 1, lines 10-13; page 2, lines 15-18; page 4, lines 1-5 and lines 19-25. While multiple embodiments are disclosed by the specification, at least some of these embodiments would include the required stimulation of only the small intestines. Applicant is plainly entitled to claim this embodiment.

Again, even though the disclosure may not provide *in haec verba* support for the claimed subject matter, there is no such requirement in order to satisfy the written description requirement. Instead, all that is required is that the originally filed disclosure would have reasonably conveyed to one having ordinary skill in the art that an inventor had possession of the concept of what is claimed. For the reasons stated above, the explicit, implicit and inherent disclosures of the specification satisfy this written description requirement. One skilled in the art would understand that the Applicants were in possession of a method involving delivery of stimulation to the small intestine alone. Therefore, Applicant respectfully requests the withdrawal of the rejection.

**Claim Rejection Under 35 U.S.C. § 102**

In the Final Office Action, the Examiner rejected claims 1-6 and 11-17 under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5,690,691). Applicant respectfully traverses the rejection. Chen et al. fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

***“consisting essentially of”***

The Final Office Action indicated that the Examiner continues to interpret “consisting essentially of” as equivalent to “comprising,” on the basis that there is no clear indication in Applicant’s disclosure of embodiments that require stimulation of only the small intestines. The Examiner maintained the position that exclusive small intestinal stimulation is not clearly disclosed because the disclosure also describes stimulation of other areas in combination with the small intestine.

Applicant respectfully disagrees with the Examiner’s disregard for the “consisting essentially of” requirement for substantially the reasons stated above with respect to the rejection under section 112, first paragraph, as well as the reasons stated in the arguments accompanying previous responses, which are hereby incorporated by reference.

MPEP 2111.03, previously cited by the Examiner, states that:

For the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.”

The specification, including the examples, provides a clear indication that electrical stimulation of the small intestines is a basic and novel characteristic of the claimed invention, as explained above with respect to the rejection under section 112, first paragraph. The examples describe electrical stimulation of the small intestine alone, and demonstrate that it is sufficient to produce the desired result of reducing food intake.

For at least these reasons, Applicant believes that the specification and claims clearly identify a basic and novel characteristic of the claimed invention as electrostimulation of the small intestine to treat obesity. Therefore, as directed by MPEP 2111.03, the Examiner should

not interpret the phrase “consisting essentially of” as equivalent to “comprising” in regard to independent claim 1 and 11. Rather, the transitional phrase "consisting essentially of" should be read to limit the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic.” MPEP 2111.03, (emphasis in original).

Chen et al. does not teach or suggest electrical stimulation of the small intestines alone wherein the electrical stimulation to the small intestines alters the patient’s natural gastric motility to prevent or slow down stomach emptying, thereby slowing food transit through the patient’s digestive system, as set forth in the claims. Accordingly, the Chen et al. reference does not anticipate claims 1-6 and 11-17 under 35 U.S.C. 102(b). Applicant respectfully requests withdrawal of the rejection.

### ***Inherent Disclosure***

Whether weight is given to “consisting essentially of” or not, the Office Action seemed to acknowledge that Chen et al. does not describe stimulation of the small intestine to slow down stomach emptying. However, the Office Action asserted that this requirement of claims 1-19 is inherent in the Chen et al. disclosure. In particular, the Office Action stated that, because the digestive tract is a closed system, slowing transit in the small intestine will inherently slow stomach emptying, thus treating obesity. The Examiner reasoned that because Chen et al. discloses small intestine stimulation to slow motility through the small intestine, it inherently discloses small intestine stimulation to also slow stomach emptying. Applicant respectfully disagrees with the conclusion.

To rely on the theory of inherency, MPEP 2112 requires that the Examiner “provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art” (emphasis in original). Applicant asserts that slowing small intestine transit in the Chen system does not necessarily result in the prevention or slowing of stomach emptying, as set forth in independent claims 1 and 11. While slowing of small intestine transit may result in the slowing of stomach emptying, “[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient.” MPEP 2112.

In Chen et al., stimulation of the small intestine is applied in conjunction with phased stimulation of the stomach. There is no mention of an embodiment in which the small intestine is stimulated alone, or stimulated to cause slowing of stomach emptying. In particular, Chen et al. does not disclose or suggest the limitation that the electrostimulation supplied to the small intestines alters the patient's gastric motility to prevent or slow down stomach emptying, thereby slowing food transit through the patient's digestive system, as required by independent claims 1 and 11. Instead, Chen et al. describes slowing down the natural peristaltic wave in an organ in the GI tract using controlled, phased, pulsing on that organ. Chen et al, Col. 7, lines 31-36. In particular, to slow down stomach emptying, Chen et al. suggests the electrostimulation of the stomach (Chen et al., Col. 6, line 66 to Col. 7, line 2), rather than stimulation of the small intestine.

In a case in which the stomach is stimulated in conjunction with the small intestine on a phased basis, it does not necessarily flow from Chen et al. that delivery of electrical stimulation to the small intestines alters the patient's natural gastric motility to prevent or slow down stomach emptying, thereby slowing food transit through the patient's digestive system, as claimed. Rather, it seems that slowing down of stomach emptying would result from the stimulation of the stomach directly in the Chen et al. system. Delivery of stimulation to the small intestine would not necessarily cause slowing down of stomach emptying, particularly in the Chen et al. system where stimulation of the small intestine is applied on a phased basis in conjunction with stimulation of the stomach. Therefore, Applicants respectfully submit that reliance on this allegedly inherent disclosure in Chen et al. is improper.

For at least these reasons, Chen et al. does not disclose or teach all elements required by independent claims 1 and 11. Additionally, all reasons provided by Applicant in previous responses are incorporated by reference. Therefore, Chen et al. does not anticipate claims 1 and 11, and the corresponding dependent claims 2-6 and 12-17. Applicant respectfully requests withdrawal of the rejection.

**Claim Rejection Under 35 U.S.C. § 103**

In the Final Office Action, the Examiner rejected claims 7-10, 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over Chen et al. in view of Mintchev et al. (US 6,449,511).

Applicant respectfully traverses the rejection.

The same deficiencies identified above with respect to Chen et al. apply to dependent claims 7-10, 18 and 19. These deficiencies are not overcome by Mintchev et al. For at least these reasons, claims 7-10, 18 and 19 are not obvious over Chen et al. in view of Mintchev et al. Applicant respectfully requests withdrawal of the rejection.

**New Claims**

Applicant has added new claims 20-26. The applied references fail to disclose or suggest the requirements of claims 20-26. For example, the applied references do not suggest a method for treatment of obesity in a patient comprising delivering electrical stimulation from an electrostimulation device to a duodenum of a patient via one or more implanted electrostimulation leads, wherein the electrical stimulation of the small intestine is selected such that the electrical stimulation of the duodenum causes an increase in volume of a stomach of the patient to substantially reduce food intake by the patient, as defined by claims 20-26. There is simply no teaching in the references that would have suggested electrical stimulation of the duodenum to cause an increase in volume of a stomach of a patient and a substantial reduction in food intake.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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